UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF ILLINOIS

\- - -

| | | |
|---|---|---|
| IN RE DEPAKOTE: | : | |
| RHEALYN ALEXANDER, | : | |
| et al., | : | No. |
| Plaintiffs, | : | 12-52-NJR-SCW |
| vs. | : | |
| ABBOTT LABORATORIES, | : | |
| INC., | : | |
| Defendant. | : | |

DEPOSITION UNDER ORAL EXAMINATION OF

PATTI NEMETH, M.D.

9:00 a.m.

Rio Rancho, New Mexico

\- - -

REPORTED BY: DANA SREBRENICK, CRR, CLR

\- - -

Golkow Technologies, Inc.

877.370.3377 ph | 917.591.5672 fax

deps@golkow.com

So that was probably the one that I would pick and it worked for -- oftentimes when we see a patient, certainly urgently, we don't really know what kind of seizures they have. We don't have a history. They're unable to give it. And we don't have the diagnostic tests. So Keppra is used for all types of seizures and so we often start with that.

MR. OTT: Let him ask another question so we get back on.

THE WITNESS: Okay.

BY MR. BROSS:

Q. So is it fair to say that you choose the drug or the treatment that's most efficacious with the least risks?

MR. KLATT: Objection, form.

A. Yes. That would be true, but we also -- when I was a neurology resident, we kind of had a scripted idea that generalized seizures would be treated by one thing and absence should be treated by another and complex partial by another; but as I say, in clinical practice, you sort of evolve into your approach to drugs.

Like, for example, Dilantin is one of the most used drugs, but it had a large number of

potential side effects so it was rarely the first choice. And epileptologists will pick some of the newer drugs that they have a better understanding of.

BY MR. BROSS:

Q. So it sounds like what you just told me is that if you have a class of drugs, the relative -- relevant risks and benefits among those drugs in a similar class are important for you to consider?

A. Yeah, yes. The class of drug is -- or -- is important particularly in things like pregnancy.

Q. So when you're looking at a drug to use, you look at all factors, all -- the totality of the drug's risks or factors?

A. I do.

Q. And in your practice, if a company knew that a drug was more dangerous for a certain population, would you expect them to let you know that?

MR. KLATT: Objection, form.

A. Well, I do know that because just in practice, you're reading and you know -- you know that Depakote has a higher risk for malformations.

Q. And I believe you actually touched on this earlier, too, I don't want to -- I'm going to try to not repeat questions I ask, so that's why I'm pausing, so if you'll excuse me. But I think you said when you place a patient on a medication, it's a decision that's made by both you and your patient?

A. That's correct.

Q. Can you describe informed consent, what it means to you?

A. That's where a patient agrees to be -- to treatment based on their knowledge of the risks and benefits as really discussed by the physician, and then the physician, of course, based on his or her information or knowledge.

Q. Then would you agree that it's -- and I think you would -- the responsibility of the physicians to give the patients the knowledge or the information they've been provided?

A. Yes.

Q. And if when you were prescribing Depakote to Ms. Sansone in 2004 you'd been provided additional information about the risks of birth defects with the use of Depakote, you would have shared that with Ms. Sansone?

she couldn't take them, I would still -- I would talk to her about it. And that's what we did.

BY MR. BROSS:

Q. And I guess my question's a little different.

A. Okay.

Q. If -- you knew about the risks that you knew at that time, but if you'd known the risks were four-fold greater, would you have shared that with Ms. Sansone?

MR. KLATT: Objection, form, foundation.

MR. OTT: He's asking if you had other information, did you talk to your patient about it.

A. Yes, I talked to the patient about new information if it applies to them.

Q. An important part of the process then is to discuss the various therapies and the benefits of the therapies and the risks of the therapies and to allow the patient to -- to have a say in the informed consent process, if you will?

A. That's right.

MR. KLATT: Objection, form.

Q. And is it fair to say that after you discuss things with your patients, ultimately it's

their decision to decide what to do?

A. Yes.

Q. So if they -- if they don't want to take something, you respect that decision?

A. Yes.

Q. I mentioned sales reps briefly. Do you know if they visited you about Depakote?

MR. OTT: That would be an Abbott rep.

MR. BROSS: It would have been an Abbott rep, sorry.

A. I don't recall.

BY MR. BROSS:

Q. Do you recall if they ever left you any studies or documents?

A. Well, I just don't recall in a general way. I know that the Depakote reps came because we would get samples in our closet, but I don't -- I just don't remember any particular conversation or --

Q. Do you know if they ever left any patient leaflets or any handout materials when they left you those samples in the closet?

A. I couldn't say for sure for that particular drug, but we did get them. They would give us promotional pages about their drugs. I

MR. KLATT: Objection, form.

A. I would say yes, but -- yes.

BY MR. BROSS:

Q. "Then, therefore, antiepilepsy drugs should be administered to women of childbearing potential only if they are clearly shown to be essential in the management of their seizures."

Does that again sound like a sort of class warning, if you will, disclosure?

MR. KLATT: Objection, form.

A. I guess -- I think it sounds like a general warning.

Q. The next paragraph, "The incidence of neural tube defects in the fetus may be increased in mothers receiving Valproate during the first trimester of pregnancy. The Centers for Disease Control, CDC, has estimated the risk of valproic acid exposed woman having children with spina bifida to be approximately 1 to 2 percent."

A. Uh-huh.

Q. Now, if the manufacturer had known that the incidence could be higher, would you have wanted to have known that?

MR. KLATT: Objection, form and foundation.

A. I would have wanted to have known that.

BY MR. BROSS:

Q. Would you have expected them to report it?

MR. KLATT: Objection, again, form and foundation. You can answer, Doctor.

THE WITNESS: Okay.

A. Yes.

Q. "Other congenital anomalies, example, craniofacial defects, cardiovascular malformations and anomalies involving various body systems compatible and incompatible with life have been reported. Sufficient data to determine the incidence of these congenital anomalies is not available."

A. Okay.

Q. And, again, I'm just asking, would you want to know the totality of the risks of a drug that you are considering using?

A. I would want to know what is -- what is known, yes.

Q. And I think we mentioned earlier or I asked you earlier if you would expect for a drug label to be accurate?

A. Well, accurate, yes.

A. Yes.

BY MR. BROSS:

Q. And may that have played a decision in your prescription decisions?

MR. KLATT: Objection, speculation.

A. Well, it would depend on the situation.

Q. But if the potential for increased congenital birth defects was actually four-fold higher, would that have been important for you to know?

MR. KLATT: Objection, form and foundation.

A. It would be important to know. But, again, without knowing exactly the situation at the time with the patient being pregnant, having seizures, tol -- not tolerating other medications, I don't know exactly what our conversation -- I know what our conversation would be about, but I don't know what the -- what decision we would come up with, but I would definitely talk to the patient.

Q. Is there anything here, though, that led you to believe or leads you to believe that Depakote is more teratogenic than other antiepileptics?

MR. KLATT: Objection, asked and answered multiple times.

MR. BROSS: I think it's different.

A. I have to read that. Let me read the whole thing again. This is the 2004, okay.

It certainly doesn't tell -- doesn't give percentages in comparisons of other drugs. It is a general statement that there is a risk -- a fetal risk with this drug.

BY MR. BROSS:

Q. I think you read my mind on -- my next question was, there's nothing in the label that tells you the overall incident rate could be higher, could be anywhere from 10 to 28 percent?

MR. KLATT: Objection, form, lack of foundation.

A. No.

Q. And I think it says there's really -- the last paragraph, insufficient data -- well, "sufficient data to determine incidence of these congenital anomalies is not available."

And I guess it was safe to say -- safe for me to assume or say that you didn't have any knowledge of these higher levels back in 2003 or 2004?

you were asked, you would not want the data and information to be speculative. And I think your answer to that is correct. But I think it's fair that you would want the data that's used and reported to be accurate about conditions and -- for medications that you're prescribing?

A. Yes.

Q. And of course, while it's true that babies could be born with or without birth defects, whether using any of the antiepileptics, you would want to know -- you would want to know the actual increased risks in forming decisions?

A. Yes, but I -- but it's broad. So I want to know of all the various types of teratogenicity, to the extent that they're known, I would, yeah.

Q. And you would take all that into account in your prescribing practices?

A. Yes.

Q. And I know there was some discussion about the pregnancy categories, pregnancy categories C and D. But within those categories, they're not actually quantifying or telling you what risks there are; is that correct?

MR. KLATT: Objection to form.